

10 vibrational therapy; and  
 11 anti-angiogenesis.

1 152. The method according to claim 148 further comprising relocating the target  
 2 tissue site by finding the bioabsorbable element.

1 153. The method according to claim 152 wherein the relocating step is carried out  
 2 by a chosen one of palpation and remote visualization.

1 154. (Amended) The method according to claim 152 wherein the relocating step is  
 2 carried out by remote visualization using at least one of ultrasound and mammography.

1 155. The method according to claim 152 wherein the relocating step is carried out  
 2 prior to the medically treating step.

1 156. The method according to claim 155 wherein the medical treating step  
 2 comprises removal of tissue.

1 157. (Amended) The method according to claim 148 wherein the positioning step is  
 2 carried out using a remotely visualizable bioabsorbable element, and wherein the relocating  
 3 step comprises guiding a treatment device to the bioabsorbable element by at least one of  
 4 remote visualization and palpation.

1 158. The method according to claim 148 wherein the medically treating step  
 2 comprises activating the site locatable by the bioabsorbable element.

1 159. The method according to claim 158 wherein the activating step is carried out  
 2 by at least one of:  
 3 injecting a radiation-emitting element at the vicinity of the target site;  
 4 externally activating a therapeutic means within the bioabsorbable element;  
 5 externally irradiating the target site; and  
 6 triggering a substance carried by the element.

1 160. The method according to claim 148 wherein the tissue sample taking step is  
 2 carried out at a biopsy site as the target tissue site.

#### REMARKS

Claims 89, 90, 92-103, 118-139, 141-148 and 150-160 remain in this case.

Obviousness-type double patenting rejections have been made for various ones of the  
 claims. Attached is a terminal disclaimer obviating this ground of rejection.

The claims have been rejected by one or more of the patents to Haaga 5,487,392,  
 Sirimanne 6,356,782 and Mavity 6,248,057.

#### The Prior Art

The patent to **Haaga 5,487,392** discloses a biopsy needle comprising an outer tubular  
 cannula 10, and inner tubular cannula 12, housed within outer cannula 10, and a solid circular  
 stylet 16, housed within the inner cannula 12. Inner cannula 12 has an outer portion 30 with a  
 sharpened end 32 and a semi-circular cut-out creating a semi-circular recess 36 which  
 supports a semi-circular hemostatic insert 14. A portion of stylet 16 spaced apart from  
 beveled tip 64 is cut away to form a specimen-cutting recess. In use, the needle is inserted  
 into the body of the patient until the distal end of the needle is adjacent a lesion 70. Stylet 16  
 is then moved axially outwardly and rotated to sever a biopsy specimen; the inner cannula 12

is moved axially outwardly to cover the specimen. This axial movement causes the hemostatic insert 14 to enter the biopsy site on the side of the needle opposite the cut specimen; see Fig. 8. At this point, insert 14 begins to swell to stop bleeding. Pulling needle from the site results in the hemostatic insert remaining at the site to swell and fill the site. The collagen is stated to be non-bioabsorbable; column 8, lines 7-9.

The patent to **Sirimanne 6,356,782** discloses a masking device 402 placed into a cavity 404, preferably through the same access sheath 400 and used to remove the tumor and create the cavity. The marking device 402 expands to fill the cavity. A marker 410 may be used to indicate the center of the cavity. The marking device 402 may be bioabsorbable and is radiopaque and/or echogenic. The marker 410 may be bioabsorbable and/or radioactive. The device may also be used to deliver drugs.

The **Mavity 6,248,057** patent discloses the use of macrostructure 10 (see Fig. 1), typically on the order of 1.0 mm, or microstructures/particles 28 (see Fig. 2), typically less than 20 micrometers. The structures are designed to provide for a chemotherapy and radiation therapy. The structure includes a bioabsorbable core 30 covered by a radiation-emitting layer 32. The drug may be in core 30 and/or layer 32. Another bioabsorbable layer may be used to cover layer 32 (see Fig. 4). The persistence period of the bioabsorbable material is usually substantially longer than the half-life of the radioactive material. "In one preferred aspect of the invention, the organ to undergo the brachytherapy is surgically debulked and the residual space filled with the radioactive bioabsorbable material which undergoes in situ gelation." Column 10, lines 61-64.

#### The Prior Art Distinguished

Independent claim 89 has been amended to incorporate the substance of claim 91. (Claim 91 has been rejected as obvious over Haaga '392 in view of Mavity '057.) Amended claims **89 and 93** now recite that the bioabsorbable element comprises a chemotherapy agent or a therapeutic gene therapy agent, respectively. In contrast, Haaga '392 only relates to placing a hemostatic insert into a biopsy void. There is no recognition that it would have been desirable to add a chemotherapy or radiation agent to the structure of Haaga '392. Haaga '392 is apparently only interested in stopping bleeding. Mavity '057 only relates to treating a site with a radiation/chemotherapy. The Mavity '057 patent has no relationship to a localization device. Therefore, the art lacks the necessary teaching or suggestion to combine the radiation/chemotherapy agents of Mavity '057 with the hemostatic insert structure of Haaga '392. With regard to **claim 94**, the cited art lacks any appropriate suggestion with

regard to subsequently receiving a therapeutic agent. Accordingly, independent claims 89, 93 and 94 are allowable over the cited art.

Independent **claim 92** recites that the therapeutic bioabsorbable element comprises a radiation element. Claim 92 is allowable for reasons similar to those discussed above with regard to claims 89 and 93. That is, Haaga '392 only relates to placing a hemostatic insert into a biopsy void. There is no recognition that it would have been desirable to add a radiation agent to the structure of Haaga '392. Mavity '057 only relates to treating a site with a radiation/chemotherapy. The Mavity '057 patent has no relationship to a localization device. Therefore, the art lacks the necessary teaching or suggestion to combine the radiation/chemotherapy agents of Mavity '057 with the structure of Haaga '392.

Independent method **claim 118** recites in part "finding the bioabsorbable element by palpation of the patient to feel the bioabsorbable element." There is nothing in the Haaga '392 or Mavity '057 patents suggesting relocating a targeted tissue by palpation. Accordingly, claim 118 is allowable over the cited art. Similarly, there is nothing in the art which suggests that aspect of method **claim 127** including "finding the bioabsorbable element by locating inflammation at the target tissue site caused by the bioabsorbable element." Claim 127 is thus also allowable over the Sirimanne '782 and Mavity '057 patents. Method **claim 136** has been amended to recite that the bioabsorbable element has a hardness of at least about 1.5 times as hard as the surrounding tissue. The cited art lacks any teaching or suggestion regarding this aspect of the invention so that claim 136 is allowable over the cited patents to Sirimanne '782 and Mavity '057.

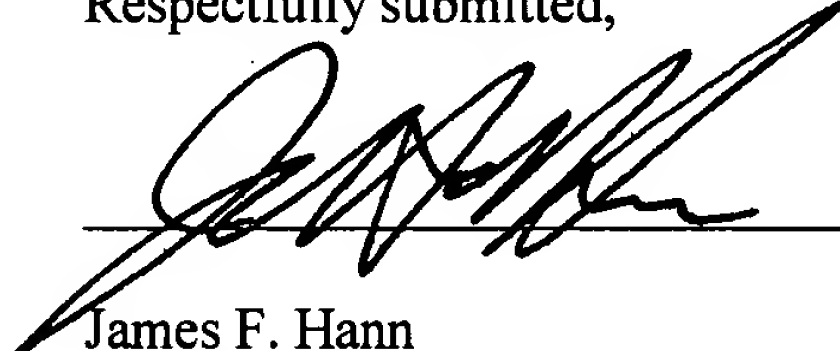
Claims 144-149, 152-157 and 160 have been rejected as anticipated by Sirimanne '782. However, the invention of claims 144-148, 152, 153, 154 as amended, 155-157 and 160 are all fully supported by the first two provisional patent applications filed on 22 June 1998 and 14 July 1998, both of which predated the December 1998 priority date of Sirimanne '782. Accordingly, Sirimanne '782 is not a proper reference for claims 144-148, 152, 153, 154 as amended, 155-157 and 160 so that the claims are all allowable over the cited reference.

The dependant claims are directed to specific novel subfeatures of the invention and are allowable for that reason as well as by depending from novel parent claims.

If the Examiner believes a telephone conversation would aid the prosecution of this case in any way, please call James F. Hann, Reg. No. 29,719, one of the attorneys of record, at (650) 712-0340.

Respectfully submitted,

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## APPENDIX

Marked-up amended claims 89, 90, 92, 93, 94, 136, 154 and 157 follow.

1           89.    (Amended) A target tissue localization device comprising:  
2                   a bioabsorbable element in a pre-delivery state prior to its delivery to a  
3 soft tissue site of a patient;  
4                   the bioabsorbable element comprising a chemotherapy agent; and  
5                   said bioabsorbable element being of a material which is in a post-delivery state  
6 at the target tissue site[, **the bioabsorbable element being remotely visualizable within the**  
7 **surrounding soft tissue when in the post-delivery state**].

1           90.    (Amended) The device according to claim 89 wherein the bioabsorbable  
2 element [**comprises a therapeutic agent**] is remotely visualizable within the surrounding  
3 soft tissue when in the post-delivery state.

1           92.    (Twice Amended) A target tissue localization device comprising:  
2                   a therapeutic bioabsorbable element in a pre-delivery state prior to its delivery  
3 to a soft tissue site of a patient;  
4                   said bioabsorbable element being of a material which is in a post-delivery state  
5 at the target tissue site[, **the bioabsorbable element being remotely visualizable within the**  
6 **surrounding soft tissue when in the post-delivery state**]; and  
7                   the therapeutic agent comprising a radiation agent.

1           93.    (Amended) A target tissue localization device comprising:  
2                   a bioabsorbable element in a pre-delivery state prior to its delivery to a  
3 soft tissue site of a patient;  
4                   **[The device according to claim 90 wherein the therapeutic agent**  
5 **comprises]** the bioabsorbable element comprising a therapeutic gene therapy agent; and  
6                   said bioabsorbable element being of a material which is in a post-delivery state  
7 at the target tissue site.

1           94.    (Amended) A target tissue localization device comprising:  
2                   a bioabsorbable element in a pre-delivery state prior to its delivery to a  
3 soft tissue site of a patient;  
4                   said bioabsorbable element being of a material which is in a post-delivery state  
5 at the target tissue site; and  
6                   **[The device according to claim 89 wherein]** the bioabsorbable element  
7 **[comprises]** comprising means for subsequently receiving a therapeutic agent.

1           136. (Amended) A target tissue localization method comprising:  
2           taking tissue from a target tissue site within a patient;  
3           selecting a bioabsorbable element that is capable of yielding therapy via  
4 delivery of therapy or activating therapy within the bioabsorbable element;  
5           positioning the bioabsorbable element at the target tissue site;  
6           the step of selecting the bioabsorbable element being carried out so that after  
7 positioning at the target site, the bioabsorbable element has a hardness of at least about 1.5  
8 times as hard as the surrounding tissue;  
9           testing the tissue; and  
10          if the testing indicates a need to do so relocating the target tissue site by  
11 finding the bioabsorbable element by remotely visualizing the bioabsorbable element.

1           154. (Amended) The method according to claim 152 wherein the relocating step is  
2 carried out by remote visualization using at least one of ultrasound[,] and mammography  
3 [and MRI].

1           157. (Amended) The method according to claim 148 wherein the positioning step is  
2 carried out using a remotely **[visulizable]** visualizable bioabsorbable element, and wherein the  
3 relocating step comprises guiding a treatment device to the bioabsorbable element by at least  
4 one of remote visualization and palpation.